

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization  
International Bureau



(43) International Publication Date  
19 December 2002 (19.12.2002)

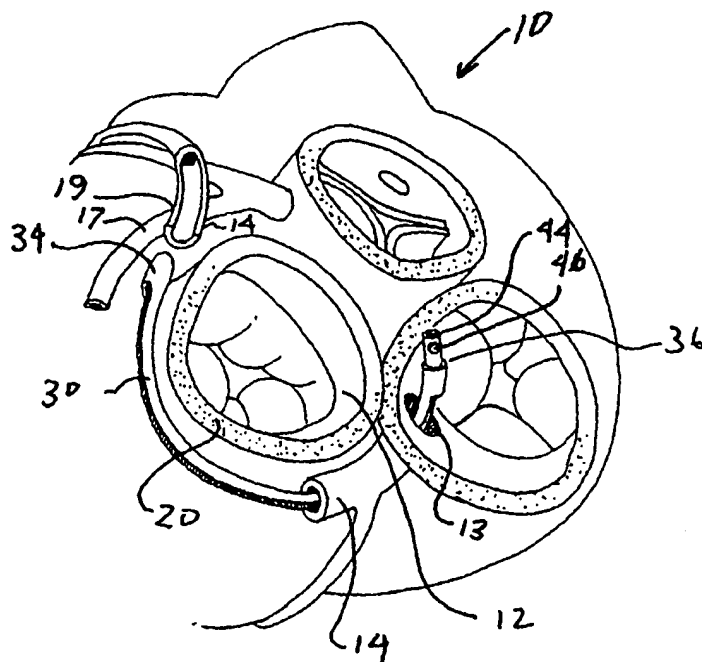
PCT

(10) International Publication Number  
**WO 02/100240 A2**

- (51) International Patent Classification<sup>7</sup>: **A61B**
- (21) International Application Number: PCT/US02/15237
- (22) International Filing Date: 13 May 2002 (13.05.2002)
- (25) Filing Language: English
- (26) Publication Language: English
- (30) Priority Data:  
09/855,945 14 May 2001 (14.05.2001) US
- (63) Related by continuation (CON) or continuation-in-part (CIP) to earlier application:  
US 09/855,945 (CON)  
Filed on 14 May 2001 (14.05.2001)
- (71) Applicant (for all designated States except US): **CARDIAC DIMENSIONS, INC.** [US/US]; Suite 100, 2018 156th Avenue Northeast, Bellevue, WA 98007 (US).
- (72) Inventors; and  
(75) Inventors/Applicants (for US only): **ALFERNES, Clifton, A.** [US/US]; 9010 - 258th Avenue Northeast, Redmond, WA 98053 (US). **ADAMS, John, M.** [US/US]; 20621 Southeast 34th Street, Sammamish, WA 98075 (US). **POWER, John, Melmoth** [AU/AU]; 65 Hannan Street, Williamstown, Melbourne, 3016 (AU).
- (74) Agents: **GRAY, Richard, O., Jr.** et al.; Graybeal Jackson Haley LLP, 155-108th Avenue Northeast, Suite 350, Bellevue, WA 98004-5973 (US).
- (81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PH, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.
- (84) Designated States (regional): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW),

[Continued on next page]

(54) Title: MITRAL VALVE THERAPY DEVICE, SYSTEM AND METHOD



(57) Abstract: An assembly and method for effecting the condition of a mitral valve annulus of a heart includes a guide wire configured to be fed into the coronary sinus of the heart, and a mitral valve annulus therapy device configured to be slidably received on the guide wire and advanced into the coronary sinus of the heart on the guide wire. A guide tube may further be employed for guiding the device into the coronary sinus. An introducer which may be employed for pushing the device into or pulling device out of the heart has a mechanism for releasably locking to the device. This enables substitution of the device if needed. Also, the crossover point of the circumflex artery and coronary sinus may be determined and avoided when the device is deployed.

WO 02/100240 A2



Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM),  
European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR,  
GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent  
(BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR,  
NE, SN, TD, TG).

*For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

**Published:**

- *without international search report and to be republished upon receipt of that report*

## MITRAL VALVE THERAPY DEVICE, SYSTEM AND METHOD

### *Field of the Invention:*

**[1]** The present invention generally relates to a device, system and  
5 method for treating a deformed heart valve. The present invention more particularly  
relates to a device, system and method for constricting or reforming a mitral valve  
annulus from within the coronary sinus to correct mitral valve dilation without  
blocking blood flow in the circumflex artery and which may be implemented using a  
10 guide wire within the coronary sinus to effect accurate device deployment and  
substitution.

**[1]**

### *Background of the Invention:*

**[2]** The human heart generally includes four valves. Of these valves, a  
most critical one is known as the mitral valve. The mitral valve is located in the left  
15 atrial ventricular opening between the left atrium and left ventricle. The mitral valve  
is intended to prevent regurgitation of blood from the left ventricle into the left atrium  
when the left ventricle contracts. In preventing blood regurgitation the mitral valve  
must be able to withstand considerable back pressure as the left ventricle contracts.

**[3]** The valve cusps of the mitral valve are anchored to muscular wall of  
20 the heart by delicate but strong fibrous cords in order to support the cusps during left  
ventricular contraction. In a healthy mitral valve, the geometry of the mitral valve  
ensures that the cusps overlies each other to preclude regurgitation of the blood  
during left ventricular contraction.

**[4]** The normal functioning of the mitral valve in preventing regurgitation  
25 can be impaired by dilated cardiomyopathy caused by disease or certain natural  
defects. For example, certain diseases may cause dilation of the mitral valve  
annulus. This can result in deformation of the mitral valve geometry to cause  
ineffective closure of the mitral valve during left ventricular contraction. Such  
ineffective closure results in leakage through the mitral valve and regurgitation.  
30 Diseases such as bacterial inflammations of the heart or heart failure can cause the  
aforementioned distortion or dilation of the mitral valve annulus. Needless to say,  
mitral valve regurgitation must not go uncorrected.

**[5]** One method of repairing a mitral valve having impaired function is to completely replace the valve. This method has been found to be particularly suitable for replacing a mitral valve when one of the cusps has been severely damaged or deformed. While the replacement of the entire valve eliminates the immediate problem associated with a dilated mitral valve annulus, presently available prosthetic heart valves do not possess the same durability as natural heart valves.

**[6]** Various other surgical procedures have been developed to correct the deformation of the mitral valve annulus and thus retain the intact natural heart valve function. These surgical techniques involve repairing the shape of the dilated or deformed valve annulus. Such techniques, generally known as annuloplasty, require surgically restricting the valve annulus to minimize dilation. Here, a prosthesis is typically sutured about the base of the valve leaflets to reshape the valve annulus and restrict the movement of the valve annulus during the opening and closing of the mitral valve.

**[7]** Many different types of prostheses have been developed for use in such surgery. In general, prostheses are annular or partially annular shaped members which fit about the base of the valve annulus. The annular or partially annular shaped members may be formed from a rigid material, such as a metal, or from a flexible material.

**[8]** While the prior art methods mentioned above have been able to achieve some success in treating mitral regurgitation, they have not been without problems and potential adverse consequences. For example, these procedures require open heart surgery. Such procedures are expensive, are extremely invasive requiring considerable recovery time, and pose the concomitant mortality risks associated with such procedures. Moreover, such open heart procedures are particularly stressful on patients with a comprised cardiac condition. Given these factors, such procedures are often reserved as a last resort and hence are employed late in the mitral regurgitation progression. Further, the effectiveness of such procedures is difficult to assess during the procedure and may not be known until a much later time. Hence, the ability to make adjustments to or changes in the prostheses to obtain optimum effectiveness is extremely limited. Later corrections, if made at all, require still another open heart surgery.

[9] An improved therapy to treat mitral regurgitation without resorting to open heart surgery has recently been proposed. This is rendered possible by the realization that the coronary sinus of a heart is near to and at least partially encircles the mitral valve annulus and then extends into a venous system including the great cardiac vein. As used herein, the term "coronary sinus" is meant to refer to not only the coronary sinus itself but in addition, the venous system associated with the coronary sinus including the great cardiac vein. The therapy contemplates the use of a device introduced into the coronary sinus to reshape and advantageously effect the geometry of the mitral valve annulus.

10 [10] The device includes a resilient member having a cross sectional dimension for being received within the coronary sinus of the heart and a longitudinal dimension having an unstressed arched configuration when placed in the coronary sinus. The device partially encircles and exerts an inward pressure on the mitral valve. The inward pressure constricts the mitral valve annulus or at least a portion of it to essentially restore the mitral valve geometry. This promotes effective valve sealing action and eliminates mitral regurgitation.

[11] The device may be implanted in the coronary sinus using only percutaneous techniques similar to the techniques used to implant cardiac leads such as pacemaker leads. The device is implanted using an elongated introducer configured for being releasably coupled to the device. The introducer is preferably flexible to permit it to advance the device into the heart and into the coronary sinus through the coronary sinus ostium. To promote guidance, an elongated sheath is first advanced into the coronary sinus. Then, the device and introducer are moved through a lumen of the sheath until the device is in position within the coronary sinus. Because the device is formed of resilient material, it conforms to the curvatures of the lumen as it is advanced through the sheath. The sheath is then partially retracted to permit the device to assume its unstressed arched configuration. Once the device is properly positioned, the introducer is then decoupled from the device and retracted through the sheath. The procedure is then completed by the retraction of the sheath. As a result, the device is left within the coronary sinus to exert the inward pressure on the mitral valve to restore mitral valve geometry.

[12] The foregoing therapy has many advantages over the traditional open heart surgery approach. Since the device, system and method may be employed in

a comparatively noninvasive procedure, mitral valve regurgitation may be treated at an early stage in the mitral regurgitation progression. Further, the device may be placed with relative ease by any minimally invasive cardiologist. Still further, since the heart remains completely intact throughout the procedure, the effectiveness of the procedure may be readily determined. Moreover, should adjustments be deemed desirable, such adjustments may be made during the procedure and before the patient is sent to recovery.

**[13]** Unfortunately, the human anatomy does impose some obstacles to this recently proposed procedure for treating mitral regurgitation. More specifically, the human heart includes a coronary artery which descends from the aorta. One branch of the coronary artery is the circumflex artery which, in turn, includes the left marginal branch of the circumflex artery. As used herein, the term "circumflex artery" is taken to include the circumflex artery itself or any branch therefrom. The circumflex artery extends distally generally along the coronary sinus but at a point proximal to the coronary artery, it passes under the coronary sinus. The circumflex artery supports blood flow important to the viability of the heart. Hence, reduction in this blood flow must be avoided. As a result, a device placed in the coronary sinus must not be permitted to extend within the coronary sinus beyond the crossover point of the circumflex artery and the coronary sinus to avoid constriction of the circumflex artery. This contemplates the need to know the location of the circumflex artery and coronary sinus crossover point. It also contemplates accurate positioning of the device within the coronary sinus to assure that the device does not extend over the circumflex artery.

**[14]** The above is further compounded by the fact that the human heart anatomy and indeed the mitral valve condition will vary from patient to patient. Hence, after deployment of an initial therapy device, the initial device effectiveness must be tested. Should a further device having different properties or configuration be deemed more efficacious, there must be provided a way to easily remove the initial device and then deploy the further device with the same deployment accuracy to avoid the crossover of the circumflex artery with the coronary sinus.

**[15]** The present invention addresses these issues. The present invention provides a therapy system and procedure which enables avoidance of the crossover of the circumflex artery with the coronary sinus by permitting accurate placement of

an initial device or any substitute device within the coronary sinus. Further to that end, the present invention enables the crossover point of the circumflex artery with the coronary sinus to be readily determined and, if desired, continuously observed during the therapy procedure. Still further, the present invention contemplates a  
5 mitral valve therapy device which is configured to avoid constricting the circumflex artery even though it passes over the circumflex artery within the coronary sinus.

### SUMMARY OF THE INVENTION

[16] The present invention provides an assembly for effecting the condition  
10 of a mitral valve annulus of a heart. The assembly includes a guide wire configured to be fed into the coronary sinus of the heart and a mitral valve annulus therapy device configured to be slidably received on the guide wire and advanced into the coronary sinus of the heart on the guide wire.

[17] The assembly may further include an elongated introducer configured  
15 to be slidingly received on the guide wire proximal to the device. The introducer may be releasably locked to the device during the deployment of the device within the coronary sinus. The assembly may further include a guide tube having an inner lumen dimensioned for receiving the guide wire and the device and introducer when the device and introducer are slidingly received on the guide wire.

[18] The assembly may still further include an elongated flexible member  
20 which is visible under X ray fluoroscopy and which may be advanced into the circumflex artery. The guide wire may also be visible under X ray fluoroscopy to reveal, under X ray fluoroscopic examination, the crossover point of the circumflex artery and the coronary sinus.

[19] The present invention still further provides a mitral valve annulus  
25 device for reshaping the mitral valve annulus to effect the condition of a mitral valve annulus of a heart. The device includes a resilient member having a cross sectional dimension for being received within the coronary sinus of a heart and having a longitudinal dimension having an arched configuration for partially encircling the  
30 mitral valve and exerting an inward pressure on the mitral valve when within the coronary sinus adjacent the mitral valve for reshaping at least a portion of the mitral valve annulus. The device includes a distal end having a bent portion to avoid

exerting pressure on the circumflex artery at the crossover point of the circumflex artery and the coronary sinus.

[20] The present invention further provides a mitral valve annulus therapy device including a generally C-shaped clip member formed of resilient material for exerting a substantially radially inward force on the mitral valve annulus when placed in the coronary sinus of a heart about and adjacent to the mitral valve. The device has a distal end including a bent portion to avoid exerting pressure on the circumflex artery at the crossover point of the circumflex artery and the coronary sinus.

[21] The present invention further provides a method of determining the crossover point of the circumflex artery and coronary sinus of a heart. The method includes the steps of inserting a first elongated flexible rod into the coronary sinus, the first rod being visible under X ray fluoroscopy, inserting a second elongated flexible rod into the circumflex artery, the second rod being visible under X ray fluoroscopy, and subjecting the heart to X ray fluoroscopic examination to determine the crossover point of the first and second rods.

[22] The present invention further provides a method of deploying a mitral valve annulus reshaping device within the coronary sinus of a heart. The method includes the steps of inserting a guide wire into the coronary sinus of the heart, and advancing an elongated mitral valve annulus constricting device on the guide wire and into the coronary sinus into a position such that the device at least partially encircles the mitral valve of the heart.

[23] The advancing step may further include the steps of slidably mounting an elongated flexible introducer onto the guide wire proximal to the device, engaging the distal end of the introducer with the proximal end of the device, and pushing the device distally into the coronary sinus with the introducer. After the device is deployed in the coronary sinus, the introducer may be withdrawn.

[24] During deployment of the device, the introducer may be releasably locked to the device. After deployment, but before the introducer is withdrawn, the introducer may be released from the device.

[25] The method may further include the steps of providing an elongated flexible guide tube having an inner lumen, the inner lumen having a cross sectional dimension greater than the cross sectional dimension of the guide wire, and feeding the guide tube into the coronary sinus of the heart over the guide wire with the guide



wire within the inner lumen of the guide tube. Thereafter, the device may be pushed along the guide wire and within the guide tube.

**[26]** The present invention further provides a method of deploying a mitral valve annulus therapy device within the coronary sinus of a heart. The method includes the steps of inserting a first wire into the circumflex artery of the heart, the first wire being visible under X ray fluoroscopy, inserting a second wire into the coronary sinus of the heart, the second wire being visible under X ray fluoroscopy, subjecting the heart to X ray fluoroscopic examination to visualize the crossover point of the first and second wires, and deploying an elongated mitral valve annulus therapy device within the coronary sinus in a position such that the distal end of the device is proximal to the crossover point of the first and second wires. Preferably, during deployment, the device is guided by the second wire into the coronary sinus.

**[27]** The method may further include the steps of slidingly mounting an elongated flexible introducer onto the second wire proximal to the device, engaging the distal end of the introducer with the proximal end of the device, and pushing the device distally into the coronary sinus with the introducer. During deployment, the introducer may be releasably locked to the device. After deployment, the introducer may be released from the device and withdrawn.

**[28]** The method may further include the steps of providing an elongated flexible guide tube having an inner lumen, the inner lumen having a cross sectional dimension greater than the cross sectional dimension of the second wire, and the guide tube being transparent to X ray fluoroscopy, and feeding the guide tube into the coronary sinus of the heart over the second wire with the second wire within the inner lumen of the guide tube. The device may then be pushed along the second wire by the introducer and within the guide tube until it reaches a desired position within the coronary sinus.

**[29]** The present invention still further provides a method of deploying a constricting device within the coronary sinus of a heart to reshape the mitral valve annulus of the heart. The method includes the steps of providing an elongated flexible guide wire having a cross sectional dimension, feeding the guide wire into the coronary sinus of the heart, providing an elongated flexible guide tube having an inner lumen, the inner lumen having a cross sectional dimension greater than the cross sectional dimension of the guide wire, and feeding the guide tube into the

coronary sinus of the heart over the guide wire with the guide wire within the inner lumen of the guide tube.

**[30]** The method further includes the steps of providing a mitral valve annulus constricting device configured to be slidably received on the guide wire and within the inner lumen of the guide tube, the device including a proximal end, providing a flexible elongated introducer configured to be slidably received on the guide wire and within the inner lumen of the guide tube, the introducer having a distal end, and placing the device onto the guide wire.

**[31]** The method still further includes the steps of placing the introducer onto the guide wire, engaging the distal end of the introducer with the proximal end of the device, pushing the device with the introducer in a distal direction along the guide wire and within the guide tube until the device is at least partially encircling the mitral valve within the coronary sinus of the heart, and withdrawing the introducer and the guide tube from the heart.

**[32]** During deployment of the device, the introducer may be releasably locked to the device. After deployment, but before the introducer is withdrawn, the introducer may be released from the device. The effectiveness of the device may then be tested.

**[33]** Should a replacement device be required, further steps to replace the device with a substitute device may be taken. Those steps may include feeding the guide tube into the coronary sinus of the heart over the guide wire and the device, feeding the introducer over the guide wire and into the guide tube, releasably locking the distal end of the introducer to the proximal end of the device, and retracting the introducer and device in a proximal direction and from the guide tube. When the device has been removed, a replacement device may then be deployed in the same manner as the initial device was deployed.

#### **BRIEF DESCRIPTION OF THE DRAWINGS**

**[34]** The features of the present invention which are believed to be novel are set forth with particularity in the appended claims. The invention, together with further aspects and advantages thereof, may best be understood by making reference to the following description taken in conjunction with the accompanying

drawings, and the several figures of which like reference numerals identify identical elements, and wherein:

[35] FIG. 1 is a superior view of a human heart with the atria removed;

[36] FIG. 2 is a perspective view of a mitral valve annulus constricting

5 device embodying the present invention;

[37] FIG. 3 is a perspective view of an assembly for deploying a mitral valve constricting device in accordance with a preferred embodiment of the present invention;

[38] FIG. 4 is another perspective view of the assembly of FIG. 3;

10 [39] FIG. 5 is a superior view of a human heart similar to that of FIG. 1 and illustrating a method of determining the crossover point of the circumflex artery and the coronary sinus in accordance with a preferred embodiment of the present invention;

[40] FIG. 6 is another view of a human heart illustrating the method of  
15 determining the crossover point of the circumflex artery and the coronary sinus in accordance with the present invention;

[41] FIG. 7 is another superior view of a human heart illustrating deployment of a mitral valve therapy device in accordance with the preferred embodiment of the present invention;

20 [42] FIG. 8 is another superior view of a human heart illustrating an implanted mitral valve therapy device embodying the present invention;

[43] FIG. 9 is another superior view of a human heart illustrating another mitral valve therapy device embodying the present invention implanted in the heart;

[44] FIG. 10 is a perspective view of another mitral valve annulus device  
25 embodying the present invention.

#### DETAILED DESCRIPTION OF THE INVENTION

[45] Referring now to FIG. 1, it is a superior view of a human heart 10 with the atria removed to expose the mitral valve 12, the coronary sinus 14, the coronary  
30 artery 15, and the circumflex artery 17 of the heart 10 to lend a better understanding of the present invention. Also generally shown in FIG. 1 are the pulmonary valve 22, the aortic valve 24, and the tricuspid valve 26 of the heart 10.

[46] The mitral valve 12 includes an anterior cusp 16, a posterior cusp 18 and an annulus 20. The annulus encircles the cusps 16 and 18 and maintains their spacing to provide a complete closure during a left ventricular contraction. As is well known, the coronary sinus 14 partially encircles the mitral valve 12 adjacent to the mitral valve annulus 20. As is also known, the coronary sinus is part of the venus system of the heart and extends along the AV groove between the left atrium and the left ventricle. This places the coronary sinus essentially within the same plane as the mitral valve annulus making the coronary sinus available for placement of the mitral valve therapy device of the present invention therein.

10 [47] Of particular importance is the physiological relationship of the coronary sinus 14 and the circumflex artery 17. The circumflex artery 17 branches from the coronary artery 15 and supplies blood flow to critical tissue of the heart 10. The circumflex artery passes beneath the coronary sinus 14 at a crossover point 19. It is one aspect of the present invention to avoid constriction of blood flow through  
15 the circumflex artery 17 when a mitral valve therapy device is deployed in the coronary sinus 14.

[48] FIG. 2 shows a mitral valve therapy device 30 embodying the present invention. As may be noted in FIG. 2, the device is elongated and has an arched configuration to at least partially encircle the mitral valve 12 adjacent to the mitral valve annulus 20 when implanted in the coronary sinus 14. The device 30 has an unstressed preformed arched radius smaller than the radius of the dilated mitral valve annulus 20. This causes the device 30 to constrict the mitral valve annulus and impart an inward, generally radial force designated by arrows 32 on the mitral valve annulus 20 when implanted in the coronary sinus of the heart. This force  
25 reshapes and returns the mitral valve annulus 20 to its original or substantially original geometry to permit the cusps 16 and 18 to more fully come together for sealing the left atrium during left ventricular contraction.

[49] The device 30 has a cross section dimension to be received by the coronary sinus. It is preferably formed of a resilient material permitting the device to  
30 be straightened and/or bent for being advanced into the coronary sinus. After being positioned within the coronary sinus, the device is permitted to assume its preformed arched configuration to act upon the mitral valve annulus as previously described. To that end, the device may be formed of, for example, Nitinol, a nickel titanium

alloy, well known in the art. This material, as is well known, is capable of being preformed but manipulated to be straight or partially bent while having sufficient memory to return to its preformed configuration. Stainless steel is also among the materials which may be used in forming the device 30. In order to be received within the coronary sinus, the device may have a cross sectional dimension of, for example, on the order of four or five french.

**[50]** With continued reference to FIG. 2, the device 30 has a distal end 34 and a proximal end 36. Between the distal end 34 and proximal end 36 the device further includes a channel 38 which is aligned with a bore 40 extending through the distal end 34 and a bore 42 extending through the proximal end 36. The proximal end 36 further includes an integral sleeve 44 which carries a protruding locking pin 46. As will be seen subsequently, the bores 40 and 42 permit the device to be slidably received by a guide wire during deployment of the device 30. The guide wire, during deployment, is confined within the channel 38.

**[51]** FIGS. 3 and 4 illustrate an assembly 50 for deploying or implanting the mitral valve therapy device 30. The assembly 50 includes a guide wire 52, a guide tube 54, and an elongated introducer 56.

**[52]** The guide wire 52 is preferably an elongated coil. It has an outer dimension to permit the guide wire 52 to be passed through the bores 40 and 42 of the device 30. This enables the device 30 to be slidably received on the guide wire 52 with the guide wire confined within the channel 38 of the device 30.

**[53]** The guide tube 54 is elongated and formed of a flexible biocompatible material. It includes an inner lumen 55 permitting the device 30 and the introducer 56 to be received therein.

**[54]** The introducer 56 preferably takes the form of an elongated coil having an inner channel dimensioned to be received by and slid onto the guide wire 52. At a distal end 58 the introducer includes a sleeve 60 which may be received over the sleeve 44 of the device 30. The introducer sleeve 60 includes a detented slot 62 for releasably receiving the pin 46 of the device 30. This enables the introducer 56 to be releasably locked to the device 30 during deployment of the device. It also permits the introducer to be relocked to the device 30 for extracting the device should it be necessary to remove the device 30 for exchange with another device.

**[55]** As previously mentioned, the circumflex artery 17 passes under the coronary sinus 14. When the device 30 is deployed, it should not be permitted to exert a force from the coronary sinus against the circumflex artery. Hence, in accordance with one embodiment of the present invention, the device is implanted within the coronary sinus at a position whereby the distal end 34 of the device 30 is proximal to the crossover point of the circumflex artery and the coronary sinus. This requires determination of the crossover point. FIGS. 5 and 6 illustrate how such a determination may be made in accordance with the present invention.

**[56]** A first elongated member, such as an elongated wire or coil wire 70 is inserted into the circumflex artery 17. The wire 70 may be formed of a material visible under X ray fluoroscopy or be of other material having a coating which is visible under X ray fluoroscopy. Next, a second wire which may be the guide wire 52 is inserted into the coronary sinus 14 by way of the ostium of coronary sinus 13. Again, the wire 52 is preferably of a material visible under X ray fluoroscopy or of another material having a coating which is visible under X ray fluoroscopy. Preferably, the wires 52 and 70 are elongated coils formed of stainless steel.

**[57]** The heart 10 or at least that portion of the heart 10 where the circumflex artery passes under the coronary sinus is subjected to X ray fluoroscopy. X ray fluoroscopy is well known in the art. The crossover point 19 where the wires 52 and 70 cross and hence where the circumflex artery and coronary sinus cross may then be readily observed by X ray fluoroscopic examination. This locates the crossover point 19 which is to be distal to the distal end 34 of the device 30 when the device 30 is positioned within the coronary sinus.

**[58]** Once the crossover point 19 has been determined, the device 30 may be deployed. During the deployment of the device, the first wire 70 may be left in the circumflex artery to permit continuous X ray fluoroscopic examination or later X ray fluoroscopic examination to confirm proper device positioning.

**[59]** FIG. 7 shows how the assembly 50 may be used to implant the device 30. Presumably the guide wire 52 has already been positioned in the coronary sinus 14 to support the determination of the circumflex artery and coronary sinus crossover point as described above. As also described above, wire 70 may also be left in the heart at this time.

**[60]** Next, the guide tube 54 is advanced into the heart. The guide tube is advanced over the guide wire 52. The guide wire hence guides the guide tube 54 into the coronary sinus where the device is to be implanted.

**[61]** When the guide tube 54 is positioned in the coronary sinus, the device 5 30 and introducer 56 are then advanced into the guide tube 54 and over the guide wire 52. The distal end 58 of the introducer 56 is first releasably locked to the proximal end 36 of the device 30 (FIGS. 3 and 4) by advancing the sleeve 60 of the introducer 56 over the sleeve 44 of the device 30 and inserting the locking pin 46 in the detented locking groove 62.

10 **[62]** With the distal end of the introducer 56 thus engaged with the proximal end of the device 30, the device may then be pushed by the introducer 56 into the coronary sinus 14 while being guided by both the guide wire 52 and the guide tube 54.

**[63]** When the device is positioned within the coronary sinus 14 with its 15 distal end proximal to the crossover point 19 and its position is confirmed by X ray fluoroscopy, the introducer may be removed. This is accomplished by turning the introducer to unlock the pin 46 and retracting the introducer from the guide tube. Then, the guide tube 54 may also be retracted leaving the device in place but still on the guide wire 52. The performance of the device 30 may now be evaluated. If 20 another device of different properties is deemed more appropriate, the device may be readily replaced. This is accomplished by reinserting the guide tube over the device, reinserting the introducer, locking the introducer to the device, and removing the device through the guide tube with the introducer. A new device may then be deployed as previously described.

25 **[64]** Once a device is deployed that satisfies the requirements of the procedure, the guide wire 52, and the wire 70 if still within the heart, may be removed. This leaves the device 30 in its proper position as illustrated in FIG. 8. Here it may be seen that the device 30 partially encircles the mitral valve 12 within the coronary sinus 14 and adjacent to the mitral valve annulus. The distal end 34 of 30 the device 30 is proximal to the crossover point 19. The proximal end 36 of the device protrudes slightly into the right atrium (not shown) through the ostium of coronary sinus 13. The sleeve 44 and pin 46 remain should subsequent removal of the device be deemed necessary.

**[65]** FIG. 9 shows another mitral valve therapy device 130 embodying the present invention. As may be noted in FIG. 9, the device is elongated and has an arched configuration to at least partially encircle the mitral valve 12 adjacent to the mitral valve annulus 20 when implanted in the coronary sinus 14. The device 130 has an unstressed preformed arched radius smaller than the radius of the dilated mitral valve annulus 20 to impart an inward, generally radial force when implanted in the coronary sinus of the heart as shown. This force again returns the mitral valve annulus 20 to its original or substantially original geometry to permit the cusps 16 and 18 to more fully come together for sealing the left atrium during left ventricular contraction.

**[66]** The device 130 has a cross sectional dimension to be received by the coronary sinus. It is also preferably formed of a resilient material to permit the device to be straightened and/or bent for being advanced into the coronary sinus. After being positioned within the coronary sinus, the device is permitted to assume its preformed arched configuration to act upon the mitral valve annulus as previously described. To that end, the device may be formed of, for example, Nitinol, a nickel titanium alloy.

**[67]** The device 130 has a distal end 134 and a proximal end 136. Between the distal end 134 and proximal end 136 the device further includes a channel 138 which is aligned with a bore 140 extending through the distal end 134 and a bore 142 extending through the proximal end 136. The proximal end 136 further includes an integral sleeve 144 which carries a protruding locking pin 146. Again, the bores 140 and 142 permit the device to be slidingly received by a guide wire during deployment of the device 130. The guide wire, during deployment, is confined within the channel 138.

**[68]** The device 130 still further includes a bend 50 at its distal end 134. As will be noted, the distal end 134 extends beyond the crossover point 19 of the circumflex artery 17 and the coronary sinus 14. However, because of the bend 150, the device is precluded from exerting constricting pressure on the circumflex artery 17 even though it extends over the crossover point 19. The device 130 may be implanted using the assembly as previously described.

**[69]** FIG. 10 shows still another mitral valve therapy device 230 embodying the present invention. Like the device 30 of FIG. 2, the device 230 is elongated and



has an arched configuration to at least partially encircle the mitral valve 12 adjacent to the mitral valve annulus 20 when implanted in the coronary sinus 14. The device 230 has an unstressed preformed arched radius smaller than the radius of the dilated mitral valve annulus 20 to impart an inward, generally radial force on the mitral valve annulus 20 when implanted in the coronary sinus of the heart to return the mitral valve annulus 20 to its original or substantially original geometry permitting the cusps of the mitral valve to more fully come together for sealing the left atrium during left ventricular contraction.

[70] The device 230 has a cross section dimension to be received by the coronary sinus. It is preferably formed of any of the resilient materials previously described.

[71] The device 230 has a distal end 234 and a proximal end 236. Between the distal end 234 and proximal end 236 the device further includes a channel 238 which is aligned with a bore 242 extending through the proximal end 236. The proximal end 236 further includes an integral sleeve 244 which carries a protruding locking pin 246. The bore 242 permits the device to be slidably received by the guide wire during deployment of the device 230. The guide wire, during deployment, is confined within the channel 238. The assembly 50 of FIGS. 3 and 4 including the guide wire 52, guide tube 54, and elongated introducer 56 may be utilized as described for deploying the device 230. Here, however, only one end of the device need be slidably received by the guide wire 52 since the device is well confined within the guide tube 54 and the guide wire 52 is confined within the channel 238.

[72] As can thus be seen from the foregoing, the present invention provides a new and improved device, assembly and method for treating mitral regurgitation.

The device may be employed with only percutaneous techniques. Further, the mitral valve therapy device may be implanted in a manner which avoids the crossover point of the circumflex artery and coronary sinus. Lastly, the effectiveness of the therapy may be immediately deduced during the implant procedure and permits substitution of devices for optimized results.

[73] While particular embodiments of the present invention have been shown and described, modifications may be made, and it is therefore intended in the appended claims to cover all such changes and modifications which fall within the true spirit and scope of the invention.

What is claimed:

1. An assembly for effecting the condition of a mitral valve annulus of a heart comprising:
  - a guide wire configured to be fed into the coronary sinus of the heart;
  - 5 and
  - a mitral valve annulus device configured to be slidably received on the guide wire and advanced into the coronary sinus of the heart on the guide wire and that reshapes the mitral valve annulus when in the coronary sinus of the heart.
- 10 2. The assembly of claim 1 wherein the guide wire is an elongated coil.
3. The assembly of claim 1 wherein the mitral valve annulus device has opposed ends and includes a guide wire engaging structure at at least one of the opposed ends.
4. The assembly of claim 3 wherein the guide wire engaging structure
- 15 includes a bore dimensioned to permit the guide wire to pass therethrough.
5. The assembly of claim 4 wherein the device further includes a guide wire confining channel extending between the opposed ends.
6. The assembly of claim 4 wherein the bore of the guide wire engaging structure is cylindrical in configuration.
- 20 7. The assembly of claim 6 wherein the device further includes a guide wire confining channel extending between the opposed ends and aligned with the bore.
8. The assembly of claim 1 wherein the guide wire is formed of a material visible under X ray fluoroscopy.
- 25 9. The assembly of claim 1 wherein at least a portion of the device is visible under X ray fluoroscopy.
10. The assembly of claim 1 wherein the device is visible under X ray fluoroscopy.
11. The assembly of claim 1 further including an elongated introducer
- 30 configured to be slidably received on the guide wire proximal to the device.
12. The assembly of claim 11 wherein the introducer is an elongated coil.
13. The assembly of claim 11 wherein the device includes a proximal end, the introducer includes a distal end, and wherein the assembly further includes a

releasable locking mechanism configured to releasably lock the proximal end of the device to the distal end of the introducer.

14. The assembly of claim 13 wherein the releasable locking mechanism includes a locking pin and a complimentary detented locking groove.

5 15. The assembly of claim 11 further including a guide tube having an inner lumen dimensioned for receiving the guide wire and the device and introducer when the device and introducer are slidably received on the guide wire.

16. A method of deploying a mitral valve annulus constricting device within the coronary sinus of a heart, the method including the steps of:

- 10 A. providing an elongated flexible guide wire having a cross sectional dimension;
- B. feeding the guide wire into the coronary sinus of the heart;
- C. providing an elongated flexible guide tube having an inner lumen, the inner lumen having a cross sectional dimension greater than the
- 15 cross sectional dimension of the guide wire;
- D. feeding the guide tube into the coronary sinus of the heart over the guide wire with the guide wire within the inner lumen of the guide tube;
- E. providing a mitral valve annulus device configured to be slidably received on the guide wire and within the inner lumen of the guide tube, the
- 20 device including a proximal end;
- F. providing a flexible elongated introducer configured to be slidably received on the guide wire and within the inner lumen of the guide tube, the introducer having a distal end;
- G. placing the device onto the guide wire;
- 25 H. placing the introducer onto the guide wire;
- I. engaging the distal end of the introducer with the proximal end of the device;
- J. pushing the device with the introducer in a distal direction along the guide wire and within the guide tube until the device is at least partially
- 30 encircling the mitral valve within the coronary sinus of the heart; and
- K. withdrawing the introducer and the guide tube from the heart.

17. The method of claim 16 wherein the engaging step includes the step I(1) of releasably locking the proximal end of the device to the distal end of the introducer.

18. The method of claim 17 including the further step J(1) of releasing the proximal end of the device from the distal end of the introducer prior to withdrawing the introducer.

19. The method of claim 18 including the further step L of testing the effectiveness of the device after the withdrawing step.

20. The method of claim 19 including the further steps of replacing the device with a further device, the replacing steps including:  
feeding the guide tube into the coronary sinus of the heart over the guide wire and the device;  
feeding the introducer over the guide wire and into the guide tube;  
releasably locking the distal end of the introducer to the proximal end of the device in a proximal direction and from the guide tube; and  
repeating steps E and G through L with a further device.

21. A method of determining the crossover point of the circumflex artery and coronary sinus of a heart, the method including the steps of:  
inserting a first elongated flexible rod into the coronary sinus, the first rod being visible under X ray fluoroscopy;  
inserting a second elongated flexible rod into the circumflex artery, the second rod being visible under X ray fluoroscopy; and  
subjecting the heart to X ray fluoroscopic examination to determine the crossover point of the first and second rods.

22. A method of deploying a mitral valve annulus therapy device within the coronary sinus of a heart, the method including the steps of:  
inserting a first wire into the circumflex artery of the heart, the first wire being visible under X ray fluoroscopy;  
inserting a second wire into the coronary sinus of the heart, the second wire being visible under X ray fluoroscopy;  
subjecting the heart to X ray fluoroscopic examination to visualize the crossover point of the first and second wires; and

deploying an elongated mitral valve annulus therapy device within the coronary sinus in a position such that the distal end of the device is proximal to the crossover point of the first and second wires.

23. The method of claim 22 wherein the deploying step includes guiding  
5 the device into the coronary sinus on the second wire.

24. The method of claim 23 wherein the deploying step further includes the steps of slidingly mounting an elongated flexible introducer onto the second wire proximal to the device, engaging the distal end of the introducer with the proximal end of the device, and pushing the device distally into the coronary sinus with the  
10 introducer.

25. The method of claim 24 including the further step of withdrawing the introducer after deploying the device.

26. The method of claim 25 wherein the engaging step includes releasably locking the proximal end of the device to the distal end of the introducer.

27. The method of claim 26 including the further step of releasing the proximal end of the device from the distal end of the introducer prior to withdrawing the introducer.

28. The method of claim 24 including the further steps of:  
providing an elongated flexible guide tube having an inner lumen, the  
20 inner lumen having a cross sectional dimension greater than the cross sectional dimension of the second wire, and the guide tube being transparent to X ray fluoroscopy;

feeding the guide tube into the coronary sinus of the heart over the second wire with the second wire within the inner lumen of the guide tube;  
25 and

wherein the pushing step includes pushing the device along the second wire and within the guide tube.

29. The method of claim 28 wherein the engaging step includes releasably locking the proximal end of the device to the distal end of the introducer.

30. The method of claim 29 including the further steps of releasing the proximal end of the device from the distal end of the introducer and withdrawing the introducer and the guide tube after deploying the device.

31. A method of deploying a mitral valve annulus reshaping device within the coronary sinus of a heart, the method including the steps of:

inserting a guide wire into the coronary sinus of the heart;

5       advancing the elongated mitral valve annulus reshaping device on the guide wire and into the coronary sinus into a position such that the device at least partially encircles the mitral valve of the heart.

32. The method of claim 31 wherein the advancing step further includes the steps of slidably mounting an elongated flexible introducer onto the guide wire proximal to the device, engaging the distal end of the introducer with the proximal  
10       end of the device, and pushing the device distally into the coronary sinus with the introducer.

33. The method of claim 32 including the further step of withdrawing the introducer after deploying the device.

34. The method of claim 33 wherein the engaging step includes releasably  
15       locking the proximal end of the device to the distal end of the introducer.

35. The method of claim 34 including the further step of releasing the proximal end of the device from the distal end of the introducer prior to withdrawing the introducer.

36. The method of claim 32 including the further steps of:  
20       providing an elongated flexible guide tube having an inner lumen, the inner lumen having a cross sectional dimension greater than the cross sectional dimension of the guide wire;

      feeding the guide tube into the coronary sinus of the heart over the guide wire with the guide wire within the inner lumen of the guide tube; and  
25       wherein the pushing step includes pushing the device along the guide wire and within the guide tube.

37. The method of claim 36 wherein the engaging step includes releasably locking the proximal end of the device to the distal end of the introducer.

38. The method of claim 37 including the further steps of releasing the  
30       proximal end of the device from the distal end of the introducer and withdrawing the introducer and the guide tube after deploying the device.

39. A mitral valve annulus device for reshaping and effecting the condition of a mitral valve annulus of a heart comprising a resilient member having a cross

sectional dimension for being received within the coronary sinus of a heart and having a longitudinal dimension having an arched configuration for partially encircling the mitral valve and exerting an inward pressure on the mitral valve when within the coronary sinus adjacent the mitral valve for reshaping at least a portion of the mitral valve annulus, the device having a distal end including a bent portion to avoid exerting pressure on the circumflex artery at the crossover point of the circumflex artery and the coronary sinus.

40. A mitral valve annulus therapy device comprising a generally C-shaped clip member formed of resilient material for exerting a substantially radially inward force on the mitral valve annulus when placed in the coronary sinus of a heart about and adjacent to the mitral valve, the device having a distal end including a bent portion to avoid exerting pressure on the circumflex artery at the crossover point of the circumflex artery and the coronary sinus.

41. An assembly for effecting the condition of a mitral valve annulus of a heart comprising:

guide wire means for extending along a predetermined path into the coronary sinus of the heart; and

mitral valve annulus reshaping means for sliding along the guide wire means and being advanced into the coronary sinus of the heart.

42. The assembly of claim 41 wherein the guide wire means comprises an elongated coil.

43. The assembly of claim 41 wherein the mitral valve annulus reshaping means has opposed ends and includes guide wire engaging means at at least one of the opposed ends.

44. The assembly of claim 43 wherein the guide wire engaging means includes a bore dimensioned to permit the guide wire means to pass therethrough.

45. The assembly of claim 44 wherein the reshaping means further includes channel means extending between the opposed ends for confining the guide wire means.

46. The assembly of claim 44 wherein the bore of the guide wire engaging means is cylindrical in configuration.

47. The assembly of claim 46 wherein the reshaping means includes guide wire channel means extending between the opposed ends and aligned with the bore for confining the guide wire means.

48. The assembly of claim 41 wherein the guide wire means is formed of a material visible under X ray fluoroscopy.

49. The assembly of claim 41 wherein at least a portion of the reshaping means is visible under X ray fluoroscopy.

50. The assembly of claim 41 wherein the reshaping means is visible under X ray fluoroscopy.

51. The assembly of claim 41 further including elongated introducer means configured to be slidably received on the guide wire means proximal to the reshaping means for pushing the reshaping means along the guide wire means.

52. The assembly of claim 51 wherein the introducer means comprises an elongated coil.

53. The assembly of claim 51 wherein the reshaping means includes a proximal end, the introducer means includes a distal end, and wherein the assembly further includes releasable locking means for releasably locking the proximal end of the reshaping means to the distal end of the introducer means.

54. The assembly of claim 53 wherein the releasable locking means comprises a locking pin and a complimentary detented locking groove.

55. The assembly of claim 51 further including guide tube means having an inner lumen dimensioned for receiving the guide wire means and the reshaping means and introducer means when the reshaping means and introducer means are slidably received on the guide wire means.

56. A mitral valve annulus constricting device for reshaping and effecting the condition of a mitral valve annulus of a heart comprising a resilient member having a cross sectional dimension for being received within the coronary sinus of a heart and having a longitudinal dimension having an arched configuration for partially encircling the mitral valve and exerting an inward pressure on the mitral valve when within the coronary sinus adjacent the mitral valve for constricting the mitral valve annulus, the device having a distal end, a proximal end, a bore through at least one of the ends, and a channel extending between the ends, the channel and bore permitting the device to be slidably received on a guide wire.



57. A mitral valve annulus therapy device comprising a generally C-shaped member formed of resilient material for exerting a substantially radially inward force on the mitral valve annulus when placed in the coronary sinus of a heart about and adjacent to the mitral valve, the device having a guide wire receiving structure that
- 5 slidingly mounts the device on a guide wire.

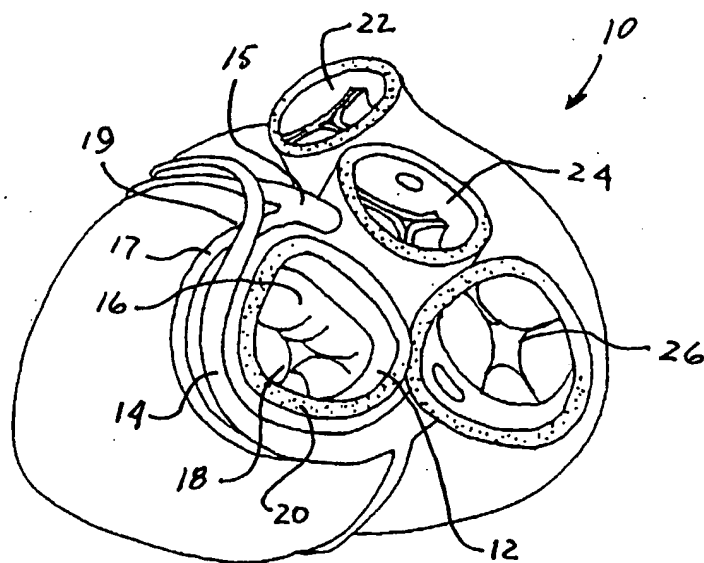


FIG. 1

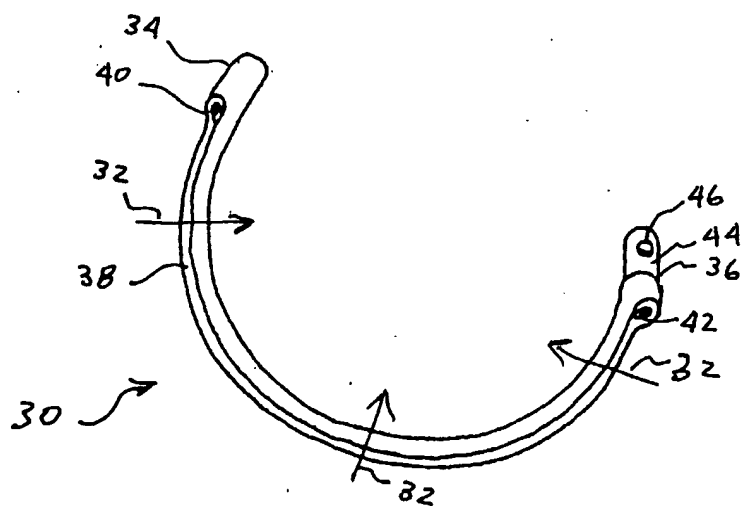


FIG. 2

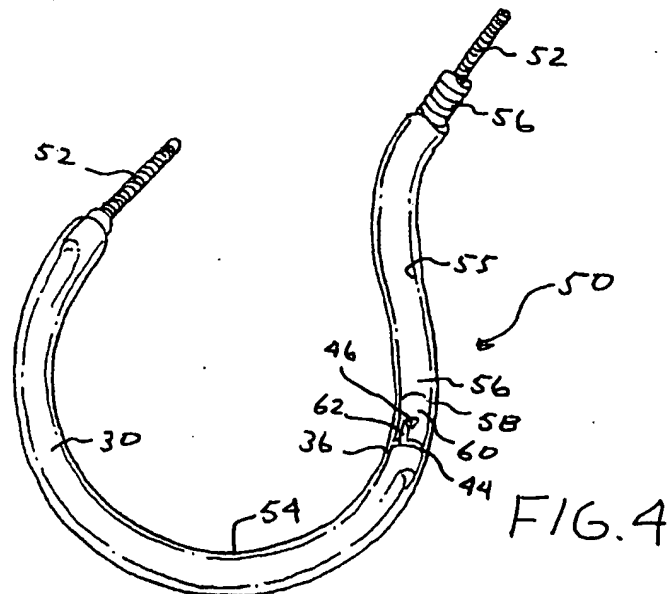
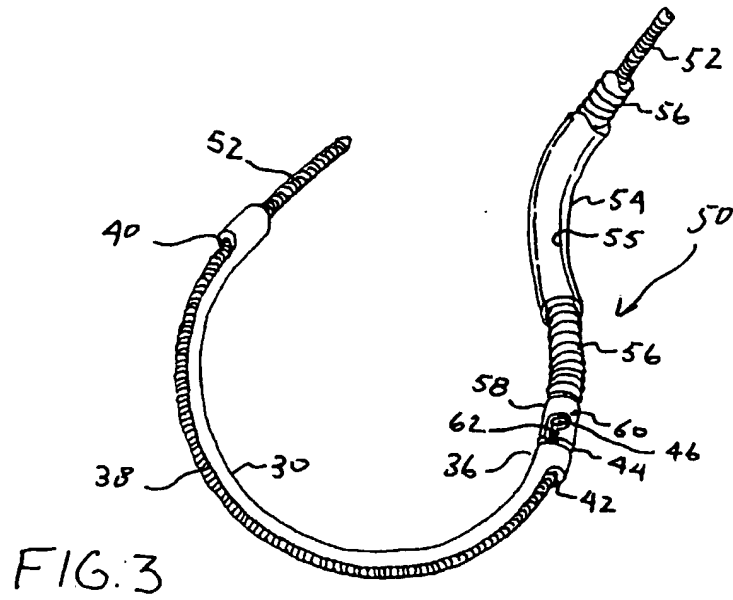


FIG. 5

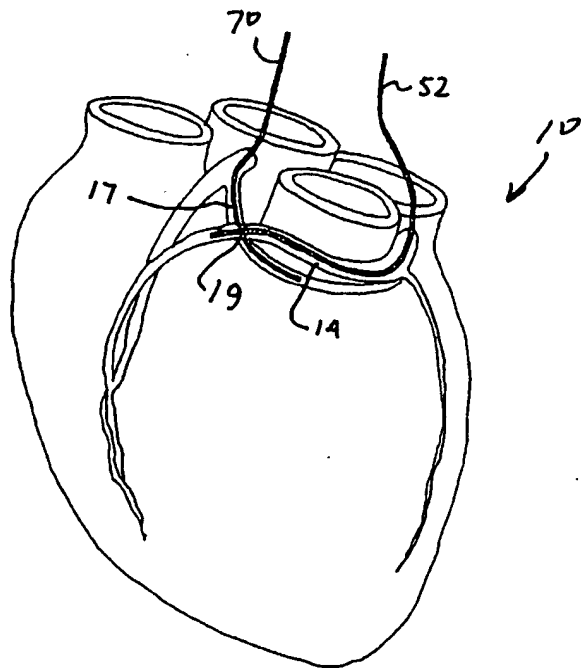
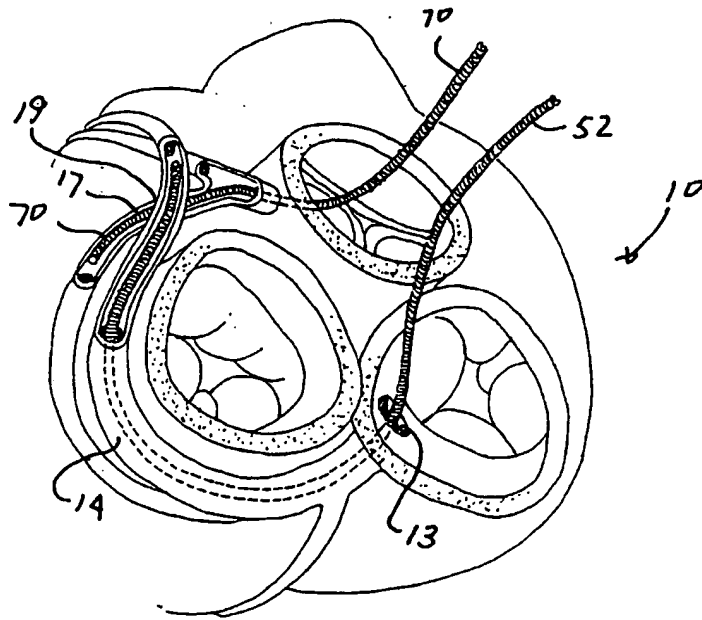


FIG. 6

FIG. 7

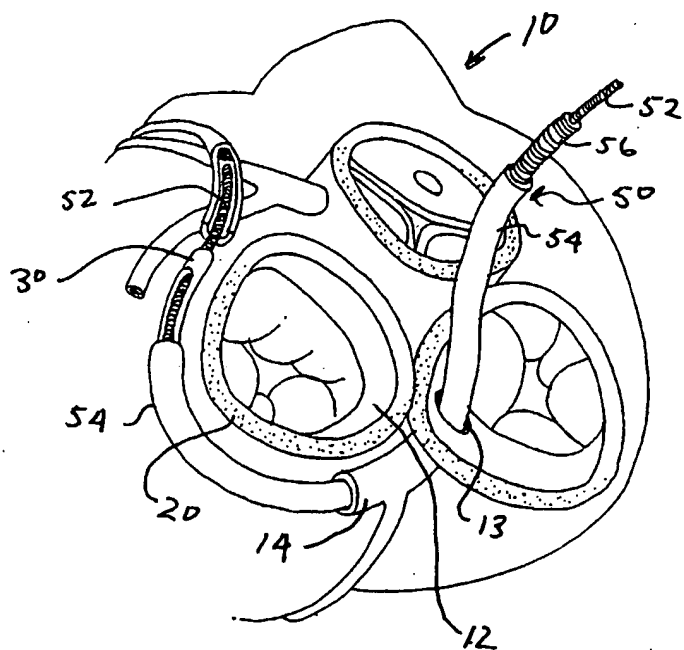
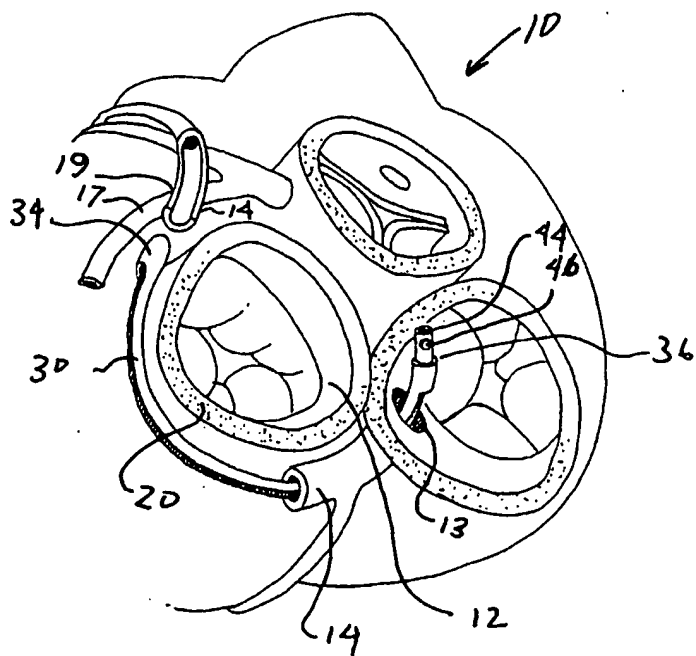


FIG. 8



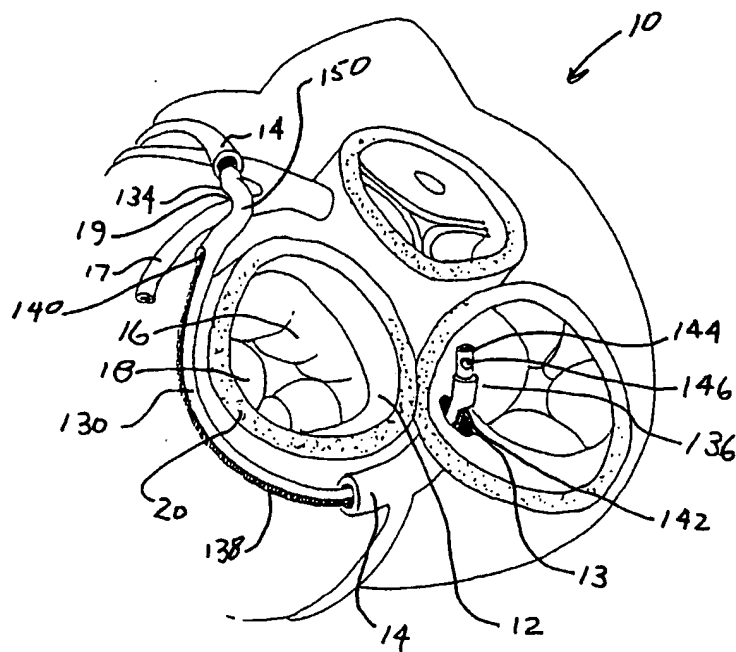


FIG. 9

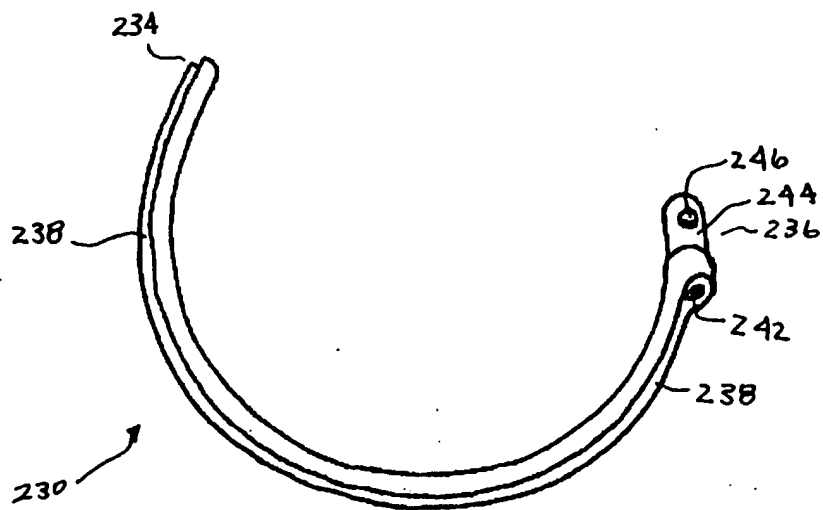


FIG. 10